

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

URL PHARMA, INC., MUTUAL
PHARMACEUTICAL COMPANY, INC. AND
UNITED RESEARCH LABORATORIES, INC.,

Case No. 15-cv-00505(PBT)

Plaintiffs,

Hon. Petrese B. Tucker

-against-

RECKITT BENCKISER INC.,

Defendant.

**MEMORANDUM OF LAW IN SUPPORT OF MOTION
BY DEFENDANT RECKITT BENCKISER TO DISMISS COMPLAINT**

BAZELON LESS & FELDMAN, P.C.
Richard L. Bazelon, Esquire
Michael A. Shapiro, Esquire
One South Broad Street, Suite 1500
Philadelphia, PA 19107
(215) 568-1155

ARENT FOX LLP
Bernice K. Leber (pro hac vice)
Michael P. McMahan (pro hac vice)
1675 Broadway
New York, NY 10019
(212) 484-3900

Attorneys for Defendant Reckitt Benckiser Inc.

TABLE OF CONTENTS

	Page
I. BACKGROUND	1
II. THE ALLEGATIONS OF THE COMPLAINT.....	3
III. LEGAL STANDARD.....	5
ARGUMENT.....	6
I. MUTUAL’S COMPLAINT FAILS TO STATE SECTION 2 SHERMAN ACT CLAIMS	6
1. The Only Exclusionary Conduct Alleged in the Complaint is a Refusal to Deal, Which Only Gives Rise to an Antitrust Duty Under Rare Circumstances, Admittedly Not Present Here	7
II. MUTUAL FAILS TO PLEAD A RELEVANT PRODUCT MARKET.....	11
III. MUTUAL HAS NOT SUFFERED “ANTITRUST INJURY” OR “ANTITRUST STANDING” AS A MATTER OF LAW.....	16
IV. MUTUAL’S STATE LAW CLAIMS FAIL AS A MATTER OF LAW.....	17
1. The Breach of Contract And Specific Performance Claims Fail As A Matter of Law	17
2. Conditions Precedent Doom The State Law Claims.....	18
3. The Settlement and Supply Agreements Are Unenforceable	20
4. The Settlement and Supply Agreements Are Unenforceable Under the U.C.C	21
V. MUTUAL’S CLAIM FOR DECLARATORY JUDGMENT IS NOT RIPE	23
CONCLUSION	24

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Acme Supply Co., Ltd. v. City of New York,</i> 39 A.D.3d 331 (N.Y. App. Div. 2007)	18
<i>American Sales v. Astra Zeneca AB,</i> 2011 WL 1465786 (S.D.N.Y. 2011).....	14
<i>Apple v. Psystar,</i> 586 F.Supp.2d 1190 (N.D.Cal. 2008)	13
<i>Ashcroft v. Iqbal,</i> 556 U.S. 662 (2009).....	2, 5, 6, 20
<i>Aspen Skiing Co. v. Aspen Highlands Skiing Corp.,</i> 472 U.S. 585 (1985).....	10
<i>Atl. Richfield Co. v. USA Petroleum Co.,</i> 495 U.S. 328 (1990).....	7, 16, 17
<i>B.V. Optische Industrie De Oude Delft v. Hologic, Inc.,</i> 909 F. Supp. 162 (S.D.N.Y. 1995)	14
<i>Baraka v. McGreevey,</i> 481 F.3d 187 (3d Cir. 2007).....	5
<i>Barton & Pittinos, Inc. v. SmithKline Beecham Corp.,</i> 118 F.3d 178 (3d Cir. 1997).....	16
<i>Bayer Schera Pharma AG v. Sandoz, Inc.,</i> No. 08 CIV.03710(PGG), 2010 WL 1222012 (S.D.N.Y. Mar. 29, 2010).....	14
<i>Bell Atlantic Corp. v. Twombly,</i> 550 U.S. 544 (2007).....	2, 5, 9
<i>Bldg. Materials Corp. of Am. v. Rotter,</i> 535 F. Supp. 2d 518 (E.D. Pa. 2008)	12
<i>Bocobo v. Radiology Consultants of South Jersey, P.A.,</i> 477 Fed. Appx. 890 (3d Cir. 2012).....	7
<i>Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.,</i> 140 F.3d 494 (3d Cir. 1998).....	12

<i>Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.,</i> 509 U.S. 209 (1993).....	8
<i>Brown Shoe Co. v. United States,</i> 370 U.S. 294 (1962).....	12
<i>Burtch v. Milberg Factors, Inc.,</i> 662 F.3d 212 (3d Cir. 2011).....	2, 6
<i>Chemtech Int'l, Inc. v. Chem. Injection Techs., Inc.,</i> 247 F.App'x 403 (3d Cir. 2007)	18
<i>City of Pittsburgh v. West Penn Power Co.,</i> 147 F.3d 256 (3d Cir. 1997).....	16
<i>Coast Cities Truck Sales, Inc. v. Navistar Int'l Transp. Co.,</i> 912 F. Supp. 747 (D.N.J. 1995)	13
<i>Coastal Aviation, Inc. v. Commander Aircraft Co.,</i> 937 F. Supp. 1051 (S.D.N.Y. 1996), <i>aff'd</i> , 108 F.3d 1369 (2d Cir. 1997)	22
<i>Coffin v. Malvern Fed. Sav. Bank,</i> 90 F.3d 851 (3d Cir. 1996).....	24
<i>Computer Assocs. Int'l, Inc. v. U.S. Balloon Mfg. Co.,</i> 10 A.D.3d 699 (2d Dep't 2004)	21
<i>Diesel Props S.r.l. v. Greystone Bus. Credit II LLC,</i> 631 F.3d 42 (2d Cir. 2011).....	18
<i>Diontech Consulting, Inc. v. New York City Hous. Auth.,</i> 78 A.D.3d 527 (N.Y. App. Div. 2010)	18
<i>Embedded Moments Inc. v. Int'l. Silver Co.,</i> 648 F. Supp. 187 (E.D.N.Y. 1986)	22
<i>Fakhoury Enters., Inc. v. J.T. Distrib.,</i> 1997 WL 291961 (S.D.N.Y. Jun. 2, 1997)	21, 22
<i>Fleer Corp. v. Topps Chewing Gum, Inc.,</i> 658 F.2d 139 (3d Cir. 1981).....	8, 10
<i>Fort v. Am. Fed'n of State, Cnty. & Mun. Emps.,</i> 375 F. App'x 109 (2d Cir. 2010)	18
<i>Gardner v. State Farm Fire & Cas. Co.,</i> 544 F.3d 553 (3d Cir. 2008)	19

<i>Giordano v. City of New York,</i> 274 F.3d 740 (2d Cir. 2001).....	24
<i>Golden v. Zwickler,</i> 394 U.S. 103 (1969).....	23
<i>Gulf States Reorganization Grp., Inc. v. Nucor Grp.,</i> 721 F.3d 1281 (11th Cir. 2013)	11
<i>Harris v. Seward Park Hous. Corp.,</i> 79 A.D.3d 425 (N.Y. App. Div. 2010)	17
<i>In re Adderall XR Antitrust Litig.,</i> 754 F.3d 128 (2d Cir. 2014).....	10, 11
<i>In Re Effexor XR Antitrust Litig.,</i> 2014 WL 4988410 (D.N.J. 2014)	6
<i>In re Horn,</i> 185 F. App'x 199 (3d Cir. 2006)	24
<i>In re Nortel Networks Inc.,</i> 737 F.3d 265 (3d Cir. 2013).....	20
<i>Int'l Commercial Res., Ltd. v. Jamaica Public Services Co., Ltd.,</i> 612 F. Supp. 1153 (S.D.N.Y. 1985).....	22
<i>Israel v. Chabra,</i> 537 F.3d 86 (2d Cir. 2008).....	19
<i>Lampe v. Xouth, Inc.,</i> No. CIV.A. 90-4067, 1991 WL 29072 (E.D.Pa. Feb. 27, 1991), <i>aff'd and remanded,</i> 952 F.2d 697 (3d Cir. 1991), <i>aff'd</i> , 9 F.3d 1540 (3d Cir. 1993)	17
<i>Lockheed Martin Corp. v. Retail Holdings, N.V.,</i> 639 F.3d 63 (2d Cir. 2011).....	20
<i>Mann v. Brenner,</i> 375 Fed. Appx. 232 (3d Cir. 2010)	5
<i>Marchese v. Cablevision Sys. Corp.,</i> No. CIV.A. 10-2190 JLL, 2012 WL 78205 (D.N.J. Jan. 9, 2012).....	14, 15
<i>Marder v. Conwed Corp.,</i> 378 F. Supp. 109 (E.D. Pa. 1974)	11
<i>McNamara v. Tourneau, Inc.,</i> 464 F. Supp. 2d 232 (S.D.N.Y. 2006).....	21

<i>Mkt. St. Sec., Inc. v. NASDAQ OMX PHLX LLC,</i> 900 F. Supp. 2d 529 (E.D. Pa. 2012)	23
<i>Molinari v. Consol Energy Inc.,</i> No. 12CV1085, 2012 WL 5932979 (W.D. Pa. Nov. 27, 2012).....	13
<i>Mumford v. GNC Franchising LLC,</i> 437 F. Supp. 2d 344 (W.D. Pa. 2006).....	13
<i>Pacific Employers Inc. Co. v. Global Reinsurance Corp. of Am.,</i> 693 F.3d 417 (3d Cir. 2012).....	18
<i>Queen City Pizza v. Domino's Pizza, Inc.,</i> 124 F.3d 430 (3d Cir. 1997).....	11, 12, 15
<i>Rohm & Haas Co. v. Permutit Co.,</i> 114 F. Supp. 846 (D. Del. 1953).....	19
<i>Santiago v. Warminster Tp.,</i> 629 F.3d 121 (3d Cir. 2010).....	3
<i>Schuylkill Energy Res. v. Penn. Power & Light Co.,</i> 113 F.3d 405 (3d Cir. 1997).....	7
<i>Sheet Metal Duct, Inc. v. Lindab, Inc.,</i> No. CIV. A. 99-6299, 2000 WL 987865 (E.D. Pa. July 18, 2000).....	8
<i>Sheils v. Pennsubry School District,</i> 2014 WL 5038395 (E.D. Pa. 2014)	2
<i>Silicon Power Corp. v. Gen. Elec. Zenith Controls, Inc.,</i> 661 F. Supp. 2d 524 (E.D. Pa. 2009)	17
<i>SmithKline Corp. v. Eli Lilly & Co.,</i> 575 F.2d 1056 (3d Cir. 1978).....	12, 13
<i>Spectrum Sports v. McQuillan,</i> 506 U.S. 447 (1993).....	12
<i>Step-Saver Data Sys., Inc. v. Wyse Tech.,</i> 912 F.2d 643 (3d Cir.1990).....	23
<i>Synthes, Inc. v. Emerge Med., Inc.,</i> No. CIV. A. 11-1566, 2012 WL 4473228 (E.D. Pa. Sept. 28, 2012)	11
<i>Texas v. United States,</i> 523 U.S. 296 (1998).....	23

<i>Townsend Oil Corp. v. Marini</i> , 77 A.D.3d 1416 (N.Y. App. Div. 2010)	22
<i>Trianco, LLC v. Int'l Bus. Machines Corp.</i> , 271 F. App'x 198 (3d Cir. 2008)	21
<i>United States v. E.I. DuPont de Nemours & Co.</i> , 351 U.S. 377 (1955).....	7
<i>United States v. Grinnell Corp.</i> , 384 U.S. 563 (1966).....	8
<i>Utilities, Inc. v. Blue Mountain Lake Associates, L.P.</i> , 121 F. App'x 947 (3d Cir. 2005)	18
<i>V. & L. Cicione, Inc. v. C. Schmidt & Sons, Inc.</i> , 403 F. Supp. 643 (E.D. Pa. 1975), <i>aff'd</i> , 565 F.2d 154 (3d Cir. 1977).	11
<i>Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP</i> , 540 U.S. 398 (2004).....	10, 11
<i>W. L. Gore & Assocs., Inc. v. Carlisle Corp.</i> , 529 F.2d 614 (3d Cir. 1976).....	8
<i>Warnick v. Home Depot U.S.A., Inc.</i> , 516 F. Supp. 2d 459 (E.D. Pa. 2007)	20
<i>Winiarski v. Duryea Assocs., LLC</i> , 14 A.D.3d 697 (N.Y. App. Div 2005)	20
<i>Yue Yu v. McGrath</i> , No. 14-1842, 2014 WL 7384328 (3d Cir. Dec. 30, 2014)	24
<i>Zenith Radio Corp. v. Hazeltine Research Inc.</i> , 395 U.S. 100 (1969).....	2, 7, 16
STATUTES	
28 U.S.C. § 1332.....	25
28 U.S.C. § 1367(c)(3).....	24
35 U.S.C. § 154.....	10
N.Y. U.C.C Art. 2	17
N.Y. UCC 2-201(1).....	21
Section 2 of the Sherman Act, 15 U.S.C. § 2.....	<i>passim</i>

OTHER AUTHORITIES

21 C.F.R. § 314.107(b)(3)(i)(A)	3
Fed .R. Civ. P. 8(a)	1, 2, 5, 20
Fed .R. Civ. P. 12(b)(6)	1, 2, 20, 21

Defendant Reckitt Benckiser Inc. (“Defendant” or “RB”), through its counsel Bazelon Less & Feldman P.C. and Arent Fox LLP, hereby respectfully submits this memorandum of law in support of its motion for an Order, pursuant to F.R.C.P. 12(b)(6) and 8(a), dismissing with prejudice the Complaint of Plaintiffs URL Pharma, Inc., Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc. (collectively “Plaintiffs” or “Mutual”).

I. BACKGROUND

Mutual’s Complaint contains three federal counts purporting to allege that RB is violating Section 2 of the Sherman Act, 15 U.S.C. §2, by unlawfully monopolizing or attempting to monopolize a relevant antitrust product market referred to in the Complaint as “ERG Product,” which includes a single product, branded Mucinex 600 mg Extended Release (“Mucinex ERG”), and its generic equivalent. Also included are three state supplemental claims for breach of contract and declaratory relief. The active ingredient in the ERG Product is guaifenesin¹. Through acquiring Adams Pharmaceutical, RB holds United States patents covering Mucinex ERG, an “over-the-counter”—i.e., sold without a doctor’s prescription—cold medication. Another generic manufacturer, Perrigo, has also been selling a generic form of Mucinex ERG, hereafter referred to as “Generic ERG Product.” Mutual bases its antitrust claims upon breach of contract allegations that RB failed to produce Generic ERG Product which Mutual claims it was entitled to buy in October 2013 pursuant to a settlement agreement. Mutual asserts that RB’s alleged actions interfered with Mutual’s ability to sell generic equivalents of Mucinex ERG in competition with RB, and in turn, caused prices to remain higher until 2014 when, as Mutual concedes, Perrigo legally entered the market with its formulation of its Generic ERG Product and as a result the price for Mucinex ERG precipitously dropped (Compl. ¶ 34).

¹ According to Webster’s Medical Dictionary, guaifenesin is a glycerol ether that is used especially as an expectorant (Merriam-Webster Dictionary) and aids in reducing bronchial secretions due to colds.

Mutual's Complaint is a transparent attempt to turn a garden-variety contractual business dispute involving RB's alleged failure to supply generic Mucinex ERG Product into a treble damage bonanza under the antitrust laws. As discussed below, breaches of contract do not form the basis for an antitrust suit under Federal Rule of Civil Procedure 12(b)(6). Mutual also ignores the well-recognized contours between the federal antitrust and patent laws. The United States Supreme Court, Federal Circuit and Third Circuit have all rejected antitrust claims that would require a patentee to forfeit its statutory right to exclude. *Zenith Radio Corp. v. Hazeltine Research Inc.*, 395 U.S. 100, 135 (1969). Mutual does not allege that RB unlawfully acquired its patents for Mucinex ERG Product, that it engaged in any unlawful conduct under the patent laws, or that it impermissibly attempted to expand its patent monopoly rights beyond the four corners of its patent. In the absence of such allegations, Mutual has stated no Section 2 claims.

The Complaint should also be dismissed with prejudice under Federal Rules of Civil Procedure 8(a). Since *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" and legal conclusions unsupported by factual allegations do not satisfy the pleading standard. *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *see also Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d.Cir 2011); *Sheils v. Pennsubry School District*, 2014 WL 5038395 (E.D.Pa. 2014) (Tucker, C.J.). Mutual's Complaint utterly fails to meet the *Iqbal/Twombly* pleading standards. It is replete with conclusory statements which do not withstand scrutiny even at this early stage of the litigation. For example, it alleges no coherent facts to justify the assertion that RB, undisputedly the lawful patent-holder for Mucinex ERG, is somehow unlawfully monopolizing that product. Mutual also offers nothing other than bald legal conclusions to support its allegation that

Mucinex ERG by itself somehow constitutes a relevant product market for antitrust purposes. Such conclusions are not accepted as true for purposes of considering the Motion to Dismiss.

II. THE ALLEGATIONS OF THE COMPLAINT²

The relevant allegations of the Complaint,³ with references to the Settlement Agreement dated March 21, 2007 (“SA”, attached as Ex. 2), are as follows:

1. “ERG” is extended-release guaifenesin, an over-the-counter drug that RB sells under the brand name Mucinex (Compl. ¶1).
2. RB held and still holds the patent for the only FDA-approved form of ERG (Compl. ¶2).⁴
3. RB has been in the business of manufacturing and selling, after it acquired Adams, Mucinex ERG. Adams has been manufacturing and selling Mucinex since before 2006 (Compl. ¶¶2, 12).
4. Mutual manufactures generic drugs. It was planning to manufacture and sell Generic ERG Product by pursuing its ANDA⁵ with the FDA seeking approval for its own generic equivalent to Mucinex ERG (Compl. ¶2, SA ¶1(q)-1(t)).

² When reviewing the allegations of the Complaint, the Court may accept as the true all of the factual allegations and may construe all reasonable inferences that can be drawn from the Complaint in Plaintiff’s favor, but should not give effect to assertions of law, or legal conclusions, masked as factual allegations. *See Santiago v. Warminster Tp.*, 629 F.3d 121, 129 (3d Cir. 2010).

³ The Complaint is attached as Exhibit 1 to the Declaration of Richard L. Bazelon, dated April 6, 2015 (“Bazelon Decl.”). All references to “Exhibit” or “Ex.” in the remainder of this brief refer to the Bazelon Decl. unless otherwise noted.

⁴ U.S. Patent No. 6,372,252.

⁵ An Abbreviated New Drug Application (ANDA) provides for the review and ultimate approval of a generic drug product. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. Generic drug applications are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). The generic version must deliver the same amount of active ingredients into a patient’s bloodstream in the same amount of time as the innovator drug. *See* <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/> (last visited April 6, 2015). Once an ANDA is filed, the patentee of the innovator drug has 45 days to challenge the infringement of the innovation patent. *See* 21 C.F.R. § 314.107(b)(3)(i)(A).

5. In 2006, in response, RB sued Mutual for patent infringement under the Hatch-Waxman Act, and in so doing, obtained an automatic 30-month stay of FDA approval of Mutual's ANDA (Compl. ¶2).
6. In 2007, RB settled its patent suit against Mutual, the terms of which such as they are, are set forth in the SA, Ex. 2.
7. As part of the settlement with Mutual, RB granted Mutual a patent license to sell Generic ERG Product pursuant to Mutual's own ANDA starting on the later of July 1, 2012 or the date Mutual obtains FDA approval to market its own ERG (SA ¶5(a)). The parties also agreed that Mutual may begin selling Generic ERG Product only upon receiving notice from RB that the first lawful commercial sale by a third-party manufacturer of generic ERG was about to occur ("Third Party").
8. Alternatively as part of the settlement with Mutual, RB granted Mutual a patent license to sell Generic ERG Product supplied by RB, provided that Mutual first obtained FDA approval to market a Generic ERG Product "corresponding to such FDA-approved Third Party formulation." (SA ¶5(b)(ii)). In that event, Mutual may elect to purchase from RB tablets of the Generic ERG Product "corresponding to such Third Party formulation" on a non-exclusive, perpetual basis (Ex. 2, SA ¶5(b)(ii)) under a Bulk Supply Agreement (SA ¶6), upon giving written notice of such election to RB.
9. Disputes arose between RB and Mutual concerning its demand for ERG on October 2013, when Perrigo admittedly determined that its Generic ERG was "unreliable" (Compl. ¶ 4) and "could not produce [the] generic ERG product." Other disputes arose over omitted terms in the SA including the formulation,

- quantity, packaging, size and shape of the ERG Product (Compl. ¶ 25, Preliminary Objections ¶¶ 34, 43 (Ex. 4)). These contract disputes led to Mutual filing a state court action over the SA.⁶
10. Mutual alleges (Compl. ¶5) that it suffered lost profits, later referred to as “consequential damages,” (Compl. ¶¶ 47, 50, 58, 64) from RB’s alleged refusal to sell Mutual the RB ERG Product.
11. Based on these disputes, Mutual claims that RB has violated Section 2 of the Sherman Act (Compl. ¶¶ 41-47; 48-50, 51-58), and breached the SA (Compl. ¶ 66-72). Mutual further seeks a declaration requiring RB to supply to Mutual other generic forms of Mucinex ERG besides 600 mg. ERG, even though those products are not yet FDA approved or legally sold (Compl. ¶¶ 74-83).

III. LEGAL STANDARD

A motion to dismiss tests the legal sufficiency of a complaint. *Mann v. Brenner*, 375 Fed. Appx. 232, 239 (3d Cir. 2010). While courts must accept as true all of a complaint’s factual allegations, courts “are not compelled to accept unsupported conclusions and unwarranted inferences.” *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007). To satisfy Rule 8a’s pleading requirements, the plaintiff must provide more than “labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Iqbal*, 556 U.S. at 678 (applying *Twombly* to all federal complaints). Instead, a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. Plausibility requires “factual content that

⁶ On August 6, 2014, Mutual filed suit for state law claims for, *inter alia*, breach of contract, under the SA in the Pennsylvania Court of Common Pleas, Commerce Program, an evident decision by Mutual not to bring an antitrust claim. After reviewing RB’s Preliminary Objections for failure to state a claim, compliance with conditions precedent, and lack of an enforceable SA or Bulk Supply Agreements, they voluntarily dismissed that action (Ex. 3 to Motion to Dismiss). On February 3, 2015, Mutual filed this federal court Complaint.

allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678 (2009). It is not sufficient for a complaint to tender ““naked assertion[s]’ devoid of further factual enhancement.”” *Id.* (quoting *Twombly*, 550 U.S. at 557). The Third Circuit and district courts recognize *Twombly*’s significance in the antitrust context. “[W]here there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.” *Burtch*, 662 F.3d at 221 (affirming dismissal of antitrust action for failure to plead plausible claim); *In Re Effexor XR Antitrust Litig.*, 2014 WL 4988410 (D.N.J. 2014) (dismissing antitrust claims arising out of a patent litigation settlement).

ARGUMENT

I.

MUTUAL’S COMPLAINT FAILS TO STATE SECTION 2 SHERMAN ACT CLAIMS

Mutual must plausibly allege RB’s exclusionary conduct to support a Section 2 Sherman Act claim. The only exclusionary conduct alleged is a refusal to deal, which, as detailed below, only gives rise to an antitrust claim in rare circumstances not present here. A patent does not create a duty to deal. In fact, a patent creates a lawful monopoly. Similarly, here the Settlement Agreement does not create a duty to deal because a breach of contract claim is not actionable under antitrust law.

Mutual alleges that RB has monopolized or attempted to monopolize the market for ERG Product in violation of Section 2 of the Sherman Act (Compl. Counts I-III). To prevail, Mutual must prove that RB “(1) possesses monopoly power in a properly defined relevant market and (2) that RB willfully acquired or maintained that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident.”

United States v. Grinnell Corp., 384 U.S. 563, 570-571 (1966); *Schuylkill Energy Res. v. Penn. Power & Light Co.*, 113 F.3d 405, 412-13 (3d Cir. 1997). In sum, Mutual must prove (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *Id.* at 413. Furthermore, Mutual must allege facts showing an injury to competition and that any injury it may have suffered was attributable to something the antitrust laws were designed to prevent. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *Bocobo v. Radiology Consultants of South Jersey, P.A.*, 477 Fed. Appx. 890, 896-897 (3d Cir. 2012).

1. The Only Exclusionary Conduct Alleged in the Complaint is a Refusal to Deal, Which Only Gives Rise to an Antitrust Duty Under Rare Circumstances, Admittedly Not Present Here

Mutual’s monopolization claims suffer from a fatal flaw. They are based entirely upon allegations that RB breached a supply contract for ERG that Mutual entered into with RB as part of settlement of patent infringement litigation. Those allegations, however, provide no proper basis for Mutual’s monopolization or attempt to monopolize claims.

First, RB holds the Mucinex ERG Patents and, thus, has a lawful patent monopoly over its product. Mutual is not challenging RB’s patent rights. (*See* SA ¶ 8.) Nor does it allege that RB is using the Mucinex ERG Patents in violation of the patent laws, or is seeking to expand the four corners of the lawfully-granted patent monopoly accorded by the Mucinex ERG Patents. Absent such allegations, RB cannot be deemed to be lawfully monopolizing or attempting to monopolize a market for Mucinex ERG where it holds a lawful patent monopoly. It merely alleges that antitrust law confers a duty upon RB to deal with Mutual.

No recognized antitrust doctrine requires a patentee to forfeit its statutory right to exclude competitors. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (“A patentee has the exclusive right to manufacture, use, and sell his invention.”); *United States v.*

E.I. DuPont de Nemours & Co., 351 U.S. 377, 392-393 (1955); *W. L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 624 (3d Cir. 1976); *Fleer Corp. v. Topps Chewing Gum, Inc.*, 658 F.2d 139, 153 (3d Cir. 1981); *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. CIV. A. 99-6299, 2000 WL 987865, at *6 (E.D. Pa. July 18, 2000) (“[T]he very purpose of a patent is precisely to give a monopoly to the inventor for a finite time, and there can be no liability under the antitrust laws for the existence or maintenance of this statutory monopoly.”).

Likewise, a claim of breach of contract with respect to licenses granted under a patent does not remove a patent’s inherent protections from antitrust liability either. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993) (“Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws; those laws do not create a federal law of unfair competition....”). Mutual’s antitrust claim cannot be based upon its allegation that RB breached the SA and acted unlawfully (Compl. ¶¶ 5, 6), even assuming that RB decided to pay contract damages in lieu of performance. Certainly an injunction does not lie under such circumstances. That is a matter of contract law, not antitrust law.

Nothing in the SA triggers an antitrust duty. The SA first states that RB granted a patent license to Mutual to sell generic equivalents to Mucinex ERG pursuant to Mutual’s own ANDAs starting on the later of July 1, 2012, or the date Mutual obtained FDA approval for its own generic ERG. The Complaint does not allege that RB in any way failed to satisfy its obligations under these parts of the SA. And it is especially worth noting that RB’s willingness to increase the number of generic ERG competitors (in the form of dealing with Mutual) once another generic company (eventually, Perrigo) started selling its own manufactured generic ERG

Product—indeed, at a time when Mutual would otherwise still have been barred from the market by the RB Mucinex Patents—is quite inconsistent with the conduct of an alleged monopolist.⁷

For the second part of the Settlement Agreement RB agreed in ¶ 5(b)(ii) that: (i) in the event Mutual did not receive FDA approval for their ANDAs as of the date another generic manufacturer was legally selling its generic ERG competing product, (ii) RB would supply Generic ERG Product for resale by Mutual, when Mutual obtained the right to market a generic ERG Product from the FDA, and (iii) the generic ERG Product which RB was to manufacture “corresponded” to the generic formulation of the third party, not to RB’s own patented Mucinex. Under such circumstances, RB agreed to permit a generic to compete when a regulatory impediment—RB’s valid patent—would have otherwise prevented Mutual from entering the market. This alleged conduct, too, is inconsistent with the conduct of an alleged monopolist.

There is again no allegation that RB refused to perform under the Agreement at issue. The Complaint and Preliminary Objections previously filed by the parties plainly show that Mutual sued in Pennsylvania Court of Common Pleas for breach of contract and specific performance, that RB had legitimate concerns over material terms missing in the SA and Bulk Supply Contract, and that Mutual failed to satisfy the three conditions precedent set forth in ¶5(b)(ii). But even assuming, *arguendo*, that RB breached the SA, this does not lead to a Sherman Act §2 claim.

⁷ That Perrigo has been lawfully selling Generic ERG Product since Fall 2014 is not disputed. Plaintiffs concede (*see* Compl. ¶4) that Perrigo publicly announced in October 2013 at the time of their demand that it was not selling its Generic ERG Product because of failed quality controls on their source of primary active ingredient guaifenesin, rendering Mutual’s state law claims implausible as a matter of law (*see infra* Point IV, and Ex. 4 ¶ 26). Given Perrigo’s failure to actually sell Generic ERG Product (Comp. ¶ 4), the obvious alternative explanation for RB’s position was Mutual’s failure to satisfy the contractual condition to show that a third party was selling legally a Generic ERG Product. That there is a lawful explanation for RB’s acts renders the Complaint implausible, particularly in light of the costs of discovery and the risks of abusive lawsuits associated with antitrust claims generally, and this case specifically. *Twombly*, 550 U.S. at 558-559.

There remains, after all, no affirmative duty to deal with competitors. In *In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014), the Second Circuit repeated the long-held rule that a manufacturer is able to “exercise his own independent discretion as to parties with whom he will deal” (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)), and thus concluded that a manufacturer had no antitrust “duty to deal” with either of the generic-drug manufacturers with whom it had agreements. *Adderall*, 754 F.3d at 135 (“The mere existence of a contractual duty to supply goods does not by itself give rise to an antitrust ‘duty to deal.’”); *see also Fleer Corp.*, 658 F.2d at 153 (3d Cir. 1981)⁸.

An affirmative antitrust duty to deal arises only under rare and limited circumstances not pleaded or present here, namely, when (1) there is a long prior course of dealing between the parties; and (2) the alleged monopolist’s actions make no economic sense absent the presence of an anti-competitive purpose. In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the Supreme Court ruled that a defendant violated Section 2 when it terminated a long-standing, profitable business relationship whereby the alleged monopolist and the plaintiff sold joint ski passes to both parties’ ski mountains. The alleged monopolist refused to renew the relationship despite the plaintiff’s offer to do so on extremely favorable market terms. But here, Mutual and RB never had a prior course of dealing before entering into the Settlement Agreement. Moreover, the three conditions triggering RB’s obligation to manufacture a generic form of Mucinex were absent; and, since 2014, Perrigo has been competing with RB. In *Verizon Commc’ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004), the Supreme Court revisited *Aspen Skiing*, elaborating that antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue, including the significance of

⁸ United States patent law contains no requirement that a patentee sell or license its invention to any one and creates no sanction for a patentee’s unilateral refusal to sell or license the invention. *See* 35 U.S.C. §154.

regulation. Verizon had no prior course of dealing with plaintiff and there was no evidence of irrational, anticompetitive conduct. The *Verizon* Complaint was lacking, like Mutual's, and was dismissed.

In sum, RB's "duty to deal" with Mutual does not arise from a duty under the antitrust laws; it arises, if at all, only through any enforceable contractual agreement they might have. (*See discussion infra.*) *In re Adderall*, 754 F.3d at 135; *V. & L. Cicione, Inc. v. C. Schmidt & Sons, Inc.*, 403 F. Supp. 643, 649 (E.D. Pa. 1975) *aff'd*, 565 F.2d 154 (3d Cir. 1977) ("The fact that a refusal to deal with a particular buyer without more, may have adverse effect upon the buyer's business does not make the refusal to deal a violation of the Sherman Act. Damages alone does not constitute liability under the Act."). That same law is dispositive here, since the Settlement Agreement is the only basis for Mutual's claim that RB must deal with it—as opposed to anyone else in the relevant market, or no one at all. *Accord Marder v. Conwed Corp.*, 378 F. Supp. 109, 111 (E.D. Pa. 1974) (manufacturer's decision to dissolve agreement with distributor was not antitrust violation, even if it was a breach of contract).

II.

MUTUAL FAILS TO PLEAD A RELEVANT PRODUCT MARKET

The Third Circuit holds that an indispensable element of Mutual's monopolization claims is a legally cognizable product market. Pleading a relevant product market is essential for assessing the potential harm to competition arising from the alleged misconduct. Such a market is alleged by affirmatively pleading those groups of producers which, because of the similarity of their products, have the actual or potential ability to take significant amounts of business away from each other. *Queen City Pizza v. Domino's Pizza, Inc.*, 124 F.3d 430, 437-438 (3d Cir. 1997), *see also Gulf States Reorganization Grp., Inc. v. Nucor Grp.*, 721 F.3d 1281, 1285-86 (11th Cir. 2013); *Synthes, Inc. v. Emerge Med., Inc.*, No. CIV. A. 11-1566, 2012 WL 4473228, at

*8 (E.D.Pa. Sept. 28, 2012). It is, thus, well-settled that a relevant product market is defined by the “reasonable interchangeability of use of the cross-elasticity of demand between the product itself and substitutes for it.” *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Reasonable interchangeability implies that one product is roughly equivalent to another for the use it is put to, even though there might be some degree of preference for one over the other. See *Spectrum Sports v. McQuillan*, 506 U.S. 447, 459 (1993) (absent proof of a relevant market, a court could not find defendant liable under §2). The criteria used to evaluate interchangeability include “industry or public recognition,” the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” *Brown Shoe*, 370 U.S. at 325.

The burden to define a relevant market rests squarely upon Mutual. When a complaint fails to allege a market that does not encompass all interchangeable substitute products, the relevant market is legally insufficient and the complaint fails. *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 514 (3d Cir. 1998); *Bldg. Materials Corp. of Am. v. Rotter*, 535 F. Supp. 2d 518, 525 (E.D. Pa. 2008). Indeed, it is common for courts to dismiss an antitrust claim for deficiency in pleading a legally sufficient relevant market. *Queen City*, 124 F.3d at 436 (“Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff’s favor, the relevant market is legally insufficient and a motion to dismiss may be granted.”)

Thus, in the pharmaceutical context, a market definition must also include “all relevant sources of supply, either actual rivals or eager potential entrants to the market.” *SmithKline*

Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063 (3d Cir. 1978). A market definition “must provide the numerator and the denominator in the fraction labeled market share.” *Id.* Mutual contends that the relevant product market is ERG Product, comprised solely of extended-release guaifenesin and its generic equivalents (Compl. ¶¶ 29-35). Mutual’s factual support for its contention that the relevant product market consists solely of the patented Mucinex Product is based solely on: (a) where the product in relation to interchangeable immediate-release guaifenesin is placed on store shelves (Compl. ¶ 30); (b) the implausible and speculative allegation that a consumer must have extended-release guaifenesin or she will let her disease go untreated (Compl. ¶ 32); and (c) RB’s response to Perrigo’s legal sale of its generic form of ERG Product in November 2014 (*i.e.*, lowering the price of Mucinex ERG) to compete, a phenomenon that generally occurs whenever a generic form of a patented drug is first sold (Compl. ¶¶ 33-34).

Mutual’s allegations fail as a matter of law. Specific factual allegations are necessary to justify the counterintuitive inference that a product is so unique that it has no actual or potential competitors. *Mumford v. GNC Franchising LLC*, 437 F. Supp. 2d 344, 355 (W.D. Pa. 2006) (“The proposed relevant market defined by plaintiffs, which does not include all reasonably interchangeably products and supplies for health nutrition stores... cannot support claims under the Sherman Act.”); *Coast Cities Truck Sales, Inc. v. Navistar Int’l Transp. Co.*, 912 F. Supp. 747, 769 (D.N.J. 1995) (“Thus, if other manufacturers either actually or conceivably could take business away... then [the] products cannot, by themselves, constitute the relevant product market.”); *Apple v. Psystar*, 586 F.Supp.2d 1190, 1198 (N.D.Cal. 2008) (“In general, a manufacturer’s own products do not themselves comprise a relevant market. A company does not violate the Sherman Act by virtue of the natural monopoly it holds over its own product.”); *Molinari v. Consol Energy Inc.*, No. 12CV1085, 2012 WL 5932979, at *6 (W.D. Pa. Nov. 27,

2012) (“Courts have frequently granted Motions to Dismiss in which the relevant market has been limited to a single entity.” (collecting cases)); *Marchese v. Cablevision Sys. Corp.*, No. CIV.A. 10-2190 JLL, 2012 WL 78205, at *24 (D.N.J. Jan. 9, 2012) (narrow single product market cannot constitute its “own, exclusive relevant market, but must include all interchangeable products,” not just “a single brand”). No such specifics are alleged here.

Not only is Mutual’s artificially narrow product market entirely unsupported in its pleading, it is also not plausible. There are over 1,500 guaifenesin-based cold products on the market.⁹ Numerous courts have rejected market allegations limited to a single, particular drug, or class of drugs, without accounting for therapeutic substitutes. *American Sales v. Astra Zeneca AB*, 2011 WL 1465786 at *3 (S.D.N.Y. 2011) (“These allegations do not plausibly allege a relevant product market consisting solely of Prilosec OTC and its generic counterpart. The plaintiff has failed to allege any product characteristics or evidence of consumer buying patterns that limit Prilosec OTC’s interchangeability of use or the cross-elasticity of demand.”); *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08 CIV.03710(PGG), 2010 WL 1222012, at *4-5 (S.D.N.Y. Mar. 29, 2010); *see also B.V. Optische Industrie De Oude Delft v. Hologic, Inc.*, 909 F. Supp. 162, 171-72 (S.D.N.Y. 1995) (dismissing complaint alleging product market as “chest equalization radiography,” since the “pleadings do not refer to any reasonably interchangeable alternatives, nor do they offer an explanation for why they are defining the relevant product market in such narrow terms.”).

Mutual readily acknowledges that there are “other cold and flu” remedies (Compl. ¶¶31, 32), but does not allege any reason they are not substitutes. It is not sufficient as a matter of law

⁹ See FDA National Drug Code Directory, Active Ingredient Search for “Guaifenesin,” available at <http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm> (last searched and accessed on April 6, 2015). Downloaded search results from this publicly-available government resource demonstrate 1553 brands of marketed over-the-counter medications containing guaifenesin as a primary active ingredient.

to show that a competing product is preferable or better. *See Queen City*, 124 F.3d at 437 (power in relevant market must arise from something other than “as a consequence of a superior product”). The product must have no market substitute at all. That is not the case here, and Mutual does not even pretend otherwise (Compl. ¶¶31, 32). Mutual has simply not sufficiently alleged plausible facts that make extended-release guaifenesin a separate product market from immediate-release guaifenesin, much less the broader cough and cold remedy market as a whole.

Likewise, “a market definition must look at all relevant sources of supply, either actual rivals or eager potential entrants to the market,” when determining the market share held by the alleged monopolist. *See Marchese v. Cablevision Sys. Corp.*, 2012 WL 78205 (D.N.J. Jan. 9, 2012) (dismissing Sherman Act § 2 claim for failure to allege a valid, relevant market, quoting *SmithKline*, 575 F.2d at 1063). As a threshold matter, Mutual does not allege any particular “numerator” or “denominator” of market share at all. But even if it did, it ignores the wide array of cold/cough medication alternatives it has already admitted exist. Indeed, besides the 1,500-plus competitors in the guaifenesin product market, the Complaint fails even to account for Perrigo’s alleged entry into the generic Mucinex market. Mutual’s market allegations are further rendered implausible when it admits that RB has had to significantly lower prices in response to Perrigo’s participation (see Compl. ¶ 34). Thus, even if the relevant market were limited to extended-release guaifenesin—a legally unsupportable proposition—the Complaint admits that RB has not maintained a monopoly.

Without pleading a relevant market, Mutual’s allegations lack a necessary predicate to finding anticompetitive effects. *E.I. du Pont*, 353 U.S. at 593.

III.

MUTUAL HAS NOT SUFFERED “ANTITRUST INJURY” OR “ANTITRUST STANDING” AS A MATTER OF LAW

Mutual’s antitrust claims also fail because Mutual has not suffered an “antitrust injury,” and thus cannot demonstrate “antitrust standing.” *See City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 264 (3d Cir. 1997). These interrelated concepts require a plaintiff not only to demonstrate that it has Article III standing, but that it has suffered “antitrust injury,” defined as “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” *Atlantic Richfield*, 495 U.S. at 334 (1990) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

Here, Mutual cannot demonstrate antitrust injury; therefore, by definition it cannot demonstrate antitrust standing. *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) (“Antitrust injury is a necessary but insufficient condition of antitrust standing. . . . Even a plaintiff who can show antitrust injury may lack antitrust standing. . . .”) (citing *Cargill Inc. v. Monfort of Col., Inc.*, 479 U.S. 104, 110 n.5 (1986)). First, conduct which allegedly eliminates competition can only cause antitrust injury if the targeted competition otherwise would be lawful. Since patents create a lawful restraint of trade, however, enforcement of a lawful patent does not violate the antitrust laws. *Zenith Radio Corp. v. Hazeltine Research, Inc.* 395 U.S. 100, 135 (1969) and Point I, *supra*. Since RB holds a valid patent on Mucinex through 2020, Mutual could not lawfully enter the market for ERG. Second, Mutual alleges that RB’s monopolization has caused higher prices, but Mutual does not allege that it has personally suffered any antitrust injury as a result, nor could it, since Mutual’s injury is concededly limited to breach of contract injury, *i.e.*, expectation damages, or the profits it

claims it would have obtained from re-selling RB's product (Compl. ¶¶5, 47, 50).¹⁰ That is not antitrust injury, and without it, Mutual does not have antitrust standing.

IV.

MUTUAL'S STATE LAW CLAIMS FAIL AS A MATTER OF LAW

Mutual's state law claims for breach of contract fail because: (i) Mutual has failed to plead compliance with conditions precedent, and cannot do so, (ii) as drafted, the SA and Supply Agreements are unenforceable agreements to agree and (iii) do not constitute a requirements contract nor a contract for the sale of goods under N.Y.U.C.C Art. 2.

1. The Breach of Contract And Specific Performance Claims Fail As A Matter of Law

To plead on a proper claim for breach of contract under New York law (Count IV of Mutual Complaint), a “... plaintiff must allege (1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages.” *Silicon Power Corp. v. Gen. Elec. Zenith Controls, Inc.*, 661 F. Supp. 2d 524, 542 (E.D. Pa. 2009) (applying NY law); *Harris v. Seward Park Hous. Corp.*, 79 A.D.3d 425, 426 (N.Y. App. Div. 2010) (same).¹¹ For the reasons set forth below, Mutual did not even plead basic compliance with contractual conditions. *Lampe v. Xouth, Inc.*, No. CIV.A. 90-4067, 1991 WL 29072, at *5 (E.D.Pa. Feb. 27, 1991), *aff'd and remanded*, 952 F.2d 697 (3d Cir. 1991), and *aff'd* 9 F.3d 1540 (3d Cir. 1993); *Chemtech Int'l, Inc. v. Chem. Injection Techs., Inc.*, 247 F.App'x 403, 405 (3d Cir. 2007). Furthermore, under New York law, a claim for specific

¹⁰ Since Mutual has not alleged antitrust injury—that is, an “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful”—it has not alleged antitrust damages, much less treble damages under Section 4 of the Clayton Act. See *Atl. Richfield*, 495 U.S. at 334 (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

¹¹ The parties expressly provided in the Settlement Agreement and the Supply Agreement that they “shall be governed by and construed in accordance with the internal laws of New York.” (Settlement Agreement at ¶ 28; Bulk Supply Agreement at ¶ 9.12)

performance is inappropriate where there exists an adequate remedy at law, namely, money damages. *Utilities, Inc. v. Blue Mountain Lake Associates, L.P.*, 121 F. App'x 947, 948-49 (3d Cir. 2005). Allegations of present, irreparable harm are also required for specific performance to be granted. *Fort v. Am. Fed'n of State, Cnty. & Mun. Emps.*, 375 F. App'x 109, 112 (2d Cir. 2010) (“as irreparable harm is ‘a common element’ required for either specific performance or injunctive relief, plaintiffs’ inability plausibly to demonstrate such imminent injury supported dismissal.”). No such actual irreparable harm is alleged in the Complaint. (Compl. ¶¶66-72.)¹²

2. Conditions Precedent Doom The State Law Claims

Significantly absent from Mutual’s Complaint are facts showing that conditions precedent set forth in the contract were met. *Pacific Employers Inc. Co. v. Global Reinsurance Corp. of Am.*, 693 F.3d 417 (3d Cir. 2012) (reversing trial court and directing dismissal of complaint under New York law for failure to comply with condition precedent); *see also Diesel Props S.r.l. v. Greystone Bus. Credit II LLC*, 631 F.3d 42, 53 (2d Cir. 2011); *Acme Supply Co., Ltd. v. City of New York*, 39 A.D.3d 331, 332 (N.Y. App. Div. 2007); *Diontech Consulting, Inc. v. New York City Hous. Auth.*, 78 A.D.3d 527, 528 (N.Y. App. Div. 2010). It is not permissible to glide over this element. Here, Mutual not only has not pleaded compliance but also cannot do so. Mutual has no claim upon which relief can be granted as a matter of law.

First, Plaintiffs did not provide the Notice required under Paragraph 6(a) of the Settlement Agreement (Ex. 2). The product identified in the alleged Notice is not the product called for in Para. 5(b)(ii) of the Settlement Agreement; namely, “tablets of the Adams Guaifenesin Product corresponding to such Third Party Formulation,” or here, the generic extended-release guaifenesin made by Perrigo. Although quoting SA ¶5(b)(ii) accurately,

¹² The allegation that Mutual “will continue to suffer irreparable harm”, even if true, nowhere includes the allegation that Mutual has been or is alleging irreparable harm. (Compl. ¶ 72.)

Mutual demands “Adams’ 600 mg guaifenesin tablets,” without the required identification that those tablets correspond a specific “Third Party Formulation.” The flaw cannot be cured after suit was brought. *See Rohm & Haas Co. v. Permutit Co.*, 114 F. Supp. 846, 848 (D. Del. 1953) (“The general rule of law is that a plaintiff’s right to recovery depends upon his right at the inception of the suit and the non-existence of a cause of action when the suit is brought is a fatal defect which cannot be cured....”).

Second, the Plaintiffs did not sign or serve the Notice. Non-parties Sun Pharma and Caraco Pharmaceutical Laboratories, Ltd., which are separate juridical entities, made the demand (*See Ex. 6*). *Gardner v. State Farm Fire & Cas. Co.*, 544 F.3d 553, 562 (3d Cir. 2008) (Federal Rule of Civil Procedure 17 provides that an “action must be prosecuted in the name of the real party in interest” and that “a court may dismiss an action for failure to prosecute in the name of the real party in interest after affording the real party in interest a reasonable time to ratify, join or be substituted in the action.”).

Third, Plaintiffs failed to plead—because they cannot plead—that they complied with three other conditions when they sent the Notice in October 2013 demanding the Adams Product from RB (Compl. ¶4). *See Israel v. Chabra*, 537 F.3d 86, 95 (2d Cir. 2008) (“Each time Plaintiffs failed to satisfy the Notice... they lost their right(s).”) Mutual baldly admits in the Complaint (¶4) that (1) the Third Party, here Perrigo, was not selling its generic form of ERG in the market in Fall 2013, because the ERG Product failed Perrigo’s quality controls; thus, it was not “lawfully” selling its form of generic guaifenesin product at the time of Mutual’s demand (*see* SA ¶5 (Ex. 2), and Ex. 4 ¶ 26); (2) Mutual pleads that there were *lawful* sales but also avers that Perrigo withdrew its Generic ERG Product from the market (and only began selling again in November 2014) (Compl. ¶¶4, 22, 23); and (3) Mutual does not—and cannot—allege that they

obtained FDA approval to market such a product as required in ¶ 5(b)(ii) of the Agreement in 2013 (*See* Ex. 2, Settlement Agreement ¶5(b)(ii) (“If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation..., then the Marketing License Effective Date shall be the date on which Mutual obtains FDA approval to market such Licensed Product corresponding to such FDA-approved Third Party Formulation.”). As this Court well knows, a Complaint, like contract terms—clearly set forth in ¶5(b)(ii)—must be given their plain meaning and read as a cohesive whole. *In re Nortel Networks Inc.*, 737 F.3d 265, 270 (3d Cir. 2013) (“New York law governs.... Thus, the agreement must be interpreted and enforced according to its plain meaning.”); *Warnick v. Home Depot U.S.A., Inc.*, 516 F. Supp. 2d 459, 477-78 (E.D. Pa. 2007) (same); *Lockheed Martin Corp. v. Retail Holdings, N.V.*, 639 F.3d 63, 69 (2d Cir. 2011) (“[I]t is important for the court to read the integrated agreement as a whole. If the document as a whole makes clear the parties’ over-all intention, courts examining isolated provisions should then choose that construction which will carry out the plain purpose and object of the agreement.”). Indeed ¶ 5(b)(ii) hinges on Mutual satisfying these three conditions precedent which Mutual fails to allege. For these reasons, the claims fail to plead Mutual’s standing under Fed.R.Civ.P 8(a) and *Iqbal*, and fail to state a claim.

3. The Settlement and Supply Agreements Are Unenforceable

Even had Mutual pleaded that it complied with the conditions properly, which it cannot, Mutual has failed to state breach of contract and specific performance claims under New York law, and therefore the Complaint must be dismissed under Fed R. Civ. P. 12(b)(6).

First, under New York law, where material terms are missing from an agreement, the contract is merely an “agreement to agree” and unenforceable. *See Winiarski v. Duryea Assocs., LLC*, 14 A.D.3d 697, 698 (N.Y. App. Div 2005); *see also McNamara v. Tourneau, Inc.*, 464 F. Supp. 2d 232, 238 (S.D.N.Y. 2006) (applying New York law, holding that a contract is

unenforceable if there is no meeting of the minds because the parties would have a different understanding of the material terms of the agreement). The SA (see ¶6(a)) and Bulk Supply Agreement, on their face, leave open the most basic and material terms, including quantity, and even clear identification of the product being purchased. *Trianco, LLC v. Int'l Bus. Machines Corp.*, 271 F. App'x 198, 201 (3d Cir. 2008) (“It is well-settled under New York law that a contract provision may be rendered an unenforceable ‘agreement to agree’ if the parties left a material term for future negotiations.”). Absent inclusion of these basic terms, both alleged contracts are unenforceable. *See Fakhouri Enters., Inc. v. J.T. Distrib.,* 1997 WL 291961, at *3 (S.D.N.Y. Jun. 2, 1997) (quoting *Judal Indus. Inc. v. Welsbach Elec. Corp.*, 138 A.D.2d 573, 574 (2d Dep’t 1988) (“[i]n a contract for the sale of goods, the essential terms are quantity, price, and time and manner of delivery”)); *Computer Assocs. Int'l, Inc. v. U.S. Balloon Mfg. Co.*, 10 A.D.3d 699, 700 (2d Dep’t 2004) (“[a] contract is unenforceable where there is no meeting of the minds between the parties regarding a material element thereof”) (citation omitted)); *Trianco*, 271 F. App'x at 202 (3d Cir. 2008) (finding agreement unenforceable where “a material term of that promise was missing”).

4. The Settlement and Supply Agreements Are Unenforceable Under the U.C.C.

The SA and Bulk Supply Agreement also fail as a matter of law under the New York Uniform Commercial Code, either as contracts for the sale of goods or requirements contracts under Fed.R.Civ.P. 12(b)(6).

Under NY UCC 2-201(1) (the Statute of Frauds), “a contract for the sale of goods for the price of \$500 or more is not enforceable by way of action or defense unless there is some writing sufficient to indicate that a contract for sale has been made between the parties and signed by the party against whom enforcement is sought.” Courts do not supply and have no discretion to

supply missing material missing terms in such contracts. *Fakhouri Enters., Inc. v. J.T. Distrib.,* 1997 WL 291961, at *3 (S.D.N.Y. Jun. 2, 1997) (quoting *Judal Indus. Inc. v. Welsbach Elec. Corp.*, 138 A.D.2d 573, 574 (N.Y. App. Div. 1988)) (“[i]n a contract for the sale of goods, the essential terms are quantity, price, and time and manner of delivery” (emphasis added)); *Embedded Moments Inc. v. Int'l. Silver Co.*, 648 F. Supp. 187, 191-192 (E.D.N.Y. 1986) (applying New York law) (evaluating a sales agreement that the Court determined to be an option agreement under the Statute of Frauds for the sale of goods); *Int'l Commercial Res., Ltd. v. Jamaica Public Services Co., Ltd.*, 612 F. Supp. 1153, 1155 (S.D.N.Y. 1985) (applying New York law) (finding an agreement to sell various goods unenforceable where the parties did not include a quantity term); *Coastal Aviation, Inc. v. Commander Aircraft Co.*, 937 F. Supp. 1051, 1061-62 (S.D.N.Y. 1996) (“the only indispensable term in such a writing is quantity,” quoting *Bazak Intern. Corp. v. Mast Industries, Inc.*, 73 N.Y.2d 113, 119 (1989)), *aff'd*, 108 F.3d 1369 (2d Cir. 1997).

If the SA and Bulk Supply Agreement are, alternatively, considered requirements contracts, they also fail as a matter of law. Under New York law, the agreement must state on its face that it is “exclusive” and must provide for reasonable quantities under NYUCC 2-306. *Embedded Moments, Inc. v. Int'l Silver Co.*, 648 F. Supp. 187, 192 (E.D.N.Y. 1986) (noting that a requirements contract is “one in which the buyer agrees to purchase his requirements exclusively from the other party to the contract”); *Townsend Oil Corp. v. Marini*, 77 A.D.3d 1416, 1416-1417 (N.Y. App. Div. 2010) (exclusivity is a mandatory element of a requirements contract). The Complaint, based on language in ¶5(b)(ii) of the SA, alleges that Mutual was granted a “non-exclusive, perpetual and irrevocable right to sell,” as well as an open-ended option to purchase an unlimited quantity of an undefined product. (SA at ¶ 6(a) (“Mutual shall

notify Adams in writing of its *election* to purchase tablets of Adams Guaifenesin Product . . .”), ¶5(b)(ii) (“Mutual, *in its sole discretion*, may purchase from Adams...”)). As such, it fails to state a claim for breach of contract (Count IV) or specific performance (Count V).

V.

MUTUAL’S CLAIM FOR DECLARATORY JUDGMENT IS NOT RIPE

Mutual’s claim for declaratory judgment (Count VI) fails because it rests upon future events and harms which have yet to occur. Mutual has not, moreover, sufficiently alleged that they are likely to occur. “A claim is not ripe [*i.e.*, premature] for adjudication as a matter of law if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal citations omitted); *Mkt. St. Sec., Inc. v. NASDAQ OMX PHLX LLC*, 900 F. Supp. 2d 529, 532 (E.D. Pa. 2012) (finding declaratory judgment claim unripe, quoting *Pittsburgh Mack Sales & Serv. Inc. v. Int’l Union of Operating Eng’rs, Local Union No. 66*, 580 F.3d 185, 190) (3d Cir. 2009)). The Third Circuit uses a three-part test to evaluate whether a declaratory judgment action is ripe, examining: 1) the adversity of the parties’ interest, 2) the conclusiveness of the judgment, and 3) the utility of that judgment. *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 912 F.2d 643, 647 (3d Cir. 1990); *see also Mkt. St. Sec., Inc.*, 900 F. Supp. 2d at 532-33.

Courts are not in the business of rendering “advisory opinions” particularly when, as here, there is no present, actual case or controversy over yet-to-be FDA approved and introduced Generic ERG Products which do not exist. *Golden v. Zwickler*, 394 U.S. 103, 108 (1969) (“The federal courts established pursuant to Article III of the Constitution do not render advisory opinions.”); *In re Horn*, 185 F. App’x 199, 202 (3d Cir. 2006) (“we are not in the business of issuing advisory opinions”); *Coffin v. Malvern Fed. Sav. Bank*, 90 F.3d 851, 853 (3d Cir. 1996)

(“The oldest and most consistent thread in the federal law of justiciability is that federal courts will not give advisory opinions.”). Under the SA ¶5(b)(ii), Mutual’s right to demand a new Generic ERG product (other than 600 mg Generic ERG Product) expressly arises only when (1) another manufacturer (third party) legally sells those FDA approved medications, (2) Mutual serves notice of its demand for that product, and (3) Mutual obtains a license to market those formulations from the FDA. Mutual has not pleaded—because it cannot plead—that another generic manufacturer has obtained FDA approval. Nor has Mutual obtained FDA approval to market other formulations of Generic ERG Product. Nor has it alleged that it served the required notice. In short, Mutual’s claim has not matured because there are no other products currently on the market other than Perrigo’s 600 mg extended release form of Mucinex (Compl. ¶ 80). The plethora of different Mucinex drugs to be produced by unnamed generic manufacturers is wildly hypothetical. Mutual cannot plausibly allege present irreparable harm with respect to these products (Compl. ¶¶ 73-83).

CONCLUSION

THIS COURT SHOULD DECLINE TO EXERCISE SUPPLEMENTAL JURISDICTION

This Court should dismiss the action in its entirety with prejudice.

However, should the Court dismiss the federal antitrust claims but, nevertheless, sustain a state law claim, the Court should, respectfully, decline to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1337(c)(3). *See Yue Yu v. McGrath*, No. 14-1842, 2014 WL 7384328, at *4 (3d Cir. Dec. 30, 2014); *Giordano v. City of New York*, 274 F.3d 740, 754 (2d Cir. 2001). In August 2014, Mutual recognized that this ordinary business dispute belongs if at all, in Pennsylvania Court of Common Pleas because it filed its alleged state law claims there. Given

the predominance of state issues and the lack of diversity jurisdiction,¹³ in the event the Court sustains any state court claim (which we believe inappropriate), we ask the Court remit this action to state court.

Dated: April 6, 2015

Respectfully submitted,

/s/ Richard L. Bazelon
Richard L. Bazelon, Esq.
Michael A. Shapiro, Esq.
BAZELON LESS & FELDMAN, P.C.
One South Broad Street, Suite 1500
Philadelphia, PA 19107
(215) 568-1155

Bernice K. Leber, Esq. (pro hac vice)
Michael P. McMahan, Esq. (pro hac vice)
AREN'T FOX LLP
1675 Broadway
New York, NY 10019
(212) 484-3900

Counsel for Defendant RB Benckiser

¹³ There is no diversity jurisdiction under 28 U.S.C. §1332 because both Plaintiffs and Defendant are residents of New Jersey. (See Compl. ¶¶ 9-12.)

CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2015, I caused true and correct copies of the foregoing Motion of Defendant Reckitt Benckiser Inc. to Dismiss Plaintiffs' Complaint, Declaration of Richard L. Bazelon, Esq., the supporting exhibit and Memorandum of Law, and a form of Order to be served upon the following counsel via the Court's ECF System:

John J. Grogan, Esq.
LANGER, GROGAN AND DIVER, PC
1717 Arch Street, Suite 4130
Philadelphia PA 19103
Attorney for Plaintiffs

s/Michael A. Shapiro
Michael A. Shapiro, Esq.